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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,566	09/14/2001	Naoki Tsuchiya	Q66152	8705

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EXAMINER

STOCKTON, LAURA LYNNE

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 02/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/936,566

**Applicant(s)**

TSUCHIYA ET AL.

**Examiner**

Laura L. Stockton, Ph.D.

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on November 8, 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 22-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22-28 is/are allowed.
- 6) ☒ Claim(s) 29-33 and 35-40 is/are rejected.
- 7) ☒ Claim(s) 34, 41 and 42 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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#### **DETAILED ACTION**

**Claims 22-42 are pending in the application.**

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 5, 2005 has been entered.

#### ***Election/Restrictions***

Applicants' election without traverse of Group IV, claims 1, 2 and 4-21 in the reply filed

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January 30, 2003 {Paper No. 8} was acknowledged in a previous Office Action.

Claims 41 and 42 were previously presented in the reply filed March 29, 2005 and are directed to an invention that is independent or distinct from the invention originally claimed for the reasons stated in the previous Office Action dated June 8, 2005.

Accordingly, methods of use not embraced by the method of instant claim 22 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Response to Arguments***

Applicants' arguments filed November 8, 2005 have been fully considered but they are not persuasive.

Applicants argue that since the methods of claims 41 and 42 are limited to the compounds recited in claims 29, 30 or 31, the Examiner is requested to rejoin

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claims 41 and 42 upon a determination that claims 29, 30 and 31 are allowable. In response, a lack of unity was made on November 5, 2002 in the instant application since the instant application is a 371. Under 371 practice, Applicants are permitted examination of one from each of the different categories of invention. Rejoinder is not applicable.

Rejections and objections made in the previous Office Action that do not appear below have been overcome. Therefore, arguments pertaining to these rejections and objections will not be addressed.

***Terminal Disclaimer***

The terminal disclaimer filed on November 8, 2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the

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expiration date of any patent resulting from 10/963,710 or 11/129,508 has been reviewed and is accepted. The terminal disclaimer has been recorded.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 29-33 and 35-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bru-Magniez et al. {U.S. Pat. 5,021,443}, Bru-Magniez et al. {U.S. Pat. 5,124,336} and Bru-Magniez et al. {U.S. Pat. 5,128,359}, each in combination with Chakravarty et al. {U.S. Pat. 5,128,327}.

***Determination of the scope and content of the prior art (MPEP***

***§2141.01)***

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Applicants claim benzimidazole products. Bru-Magniez et al. '443 (columns 1, 2 and 11; and especially Example 63 in column 29 and Example 84 in column 32), Bru-Magniez et al. '336 (columns 1, 2, 11 and 12; and especially Example 59 in column 41 and Example 147 in column 53) and Bru-Magniez et al. '359 (columns 1, 2, 11 and 12; and especially Example 64 in column 41 and Example 84 in column 47) each teach benzimidazole products, that are structurally similar to the instant claimed products, which are useful in treating heart failure.

***Ascertainment of the difference between the prior art and the claims***  
***(MPEP §2141.02)***

The difference between the compounds of Bru-Magniez et al. '443, Bru-Magniez et al. '336 and Bru-Magniez et al. '359 and the instant claimed compounds is that the compounds in instant independent claim 29 require where M is a sulfinyl or sulfonyl group and the prior art teaches sulfur. Or, in the case of instant independent

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claim 31,  $X^1$  and  $X^2$  must represent substituents such as  $-\text{CH}_2\text{NH}_2$ ,  $-\text{CONR}^1\text{R}^2$ , etc., in which Bru-Magniez et al. '443, Bru-Magniez et al. '336 and Bru-Magniez et al. '359 do not teach.

However, Chakravarty et al. teach the interchangeability of sulfur, sulfinyl and sulfonyl {see variable E, definition b)} in column 4, line 38 in benzimidazole compounds (column 2) that are useful in treating, for example, heart failure (column 1, lines 63-68; and column 2, lines 1-5). Further, Chakravarty et al. teach the interchangeability of the benzimidazole core being unsubstituted or substituted with substituents such as alkyl,  $-\text{NO}_2$ ,  $-\text{CH}_2\text{NH}_2$ ,  $-\text{COOH}$ , COOalkyl and  $-\text{CONH}_2$  (see the definitions of  $-\text{A}^1-\text{A}^2-\text{A}^3-\text{A}^4-$  and of the  $\text{R}^4$  variable in columns 3-5).

***Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)***

One skilled in the art would thus be motivated to prepare compounds embraced by Bru-Magniez et al. '443, Bru-Magniez et al. '336 and Bru-Magniez et al. '359,



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especially in view of the teachings in Chakravarty et al., to arrive at the instant claimed compounds with the expectation of obtaining additional beneficial compounds that would be useful in treating diseases/disorders such as heart failure. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

### ***Response to Arguments***

Applicants' arguments filed November 8, 2005 have been considered. Applicants argue that: (1) since the instant J variable definition has been amended to exclude phenyl, the compounds of the prior art differ from the compounds instantly claimed at the instant "M", "J" and part of "X<sup>1</sup> and X<sup>2</sup>" variable positions; and (2) the activities of the compounds of the prior art

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are different than the activity of the instant claimed compounds.

Applicants' arguments have been considered but have not been found persuasive. Although the definition of the J variable has been amended, each of Bru-Magniez et al. '443 (column 1, lines 60-61; and especially Example 84 in column 32), Bru-Magniez et al. '336 (column 1, lines 59-61; and especially Example 147 in column 53) and Bru-Magniez et al. '359 (column 1, lines 61-62; and especially Example 84 in column 47) also teach a naphthyl ring at this position. See in each of the references where  $X_3$  and  $X_4$  form a naphthalene with the phenyl. The other differences have been discussed above. Further, there is no requirement that the prior art must suggest that the claimed product will have the same or similar utility as that discovered by applicant in order to support a legal conclusion of obviousness. In re Dillon, 16 U.S.P.Q. 2d 1897, 1904 (Fed. Cir.

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1990). For all the reasons given above, the rejection is maintained.

***Allowable Subject Matter***

Claims 22-28 are allowed over the art of record.

Claim 34 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 41 and 42 are objected to for containing non-elected subject matter.

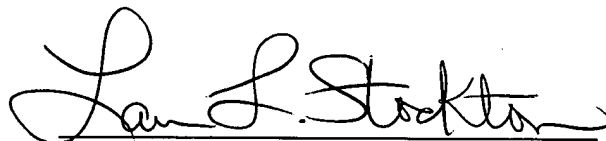
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached

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on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

A handwritten signature in cursive script, reading "Laura L. Stockton".

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

February 15, 2006